

EXHIBIT A

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICAID DRUG PRICE
COMPARISON:
AVERAGE SALES PRICE TO
AVERAGE WHOLESALE PRICE**



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Inspector General

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OEI-03-05-00200

Office of Inspector General

<http://oig.hhs.gov>

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EXECUTIVE SUMMARY

OBJECTIVE

To compare average sales price (a statutorily defined price based on actual sales transactions) to average wholesale price (the published price most States use to set Medicaid reimbursement rates) for Medicare-covered drugs.

BACKGROUND

Increases in Medicaid's prescription drug costs have generated considerable attention from the Administration, Congress, and the States. Federal regulations require that each State's reimbursement for Medicaid prescription drugs not exceed the lower of (1) its estimated acquisition cost plus a dispensing fee, or (2) the provider's usual and customary charge to the public for the drug.

Currently, most States estimate acquisition cost by discounting the average wholesale price (AWP) by a certain percentage. A small number of States use wholesale acquisition cost (WAC) plus a percentage markup when determining estimated acquisition cost. The AWP is a published price reported in commercial publications. Similarly, the WAC is a price reported in commercial publications. Prior to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Public Law 108-173), WAC was not a term defined in statute or regulation. The MMA defined WAC as the manufacturer's list price for the drug to wholesalers or direct purchasers, not including prompt pay or other discounts, rebates, or reductions in price, for the most recent month for which information is available.

Previous Office of Inspector General work demonstrated that the AWP States use to establish their Medicaid drug reimbursement rates are higher than the prices retail pharmacies pay to purchase drugs. The AWP is not defined in law or regulation, and fails to account for the discounts available to various payers.

Prior to 2005, Medicare also used the AWP as the basis for Part B drug reimbursement. As of January 1, 2005, the MMA changed the basis of reimbursement for prescription drugs from AWP to average sales price (ASP).

Unlike AWP and WAC, there is a specific method to calculate ASP defined in the MMA and the Social Security Act (the Act). Pursuant to

section 1847A(c) of the Act, as amended by the MMA, the ASP is a manufacturer's unit sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that same quarter. The ASP is net of any price concessions such as volume, prompt pay, and cash discounts. Certain sales are exempt from the calculation of ASP, including sales at a nominal charge. Similar to ASP, average manufacturer price (AMP) is defined in the Act and based on actual sales. Section 1927(k)(1) of the Act defines AMP as the average price paid to the manufacturer by wholesalers in the United States for drugs distributed to the retail pharmacy class of trade, minus customary prompt pay discounts. Medicaid uses AMP data reported quarterly by manufacturers to determine the rebate amount for a drug.

The President's 2006 Budget proposes to require State Medicaid programs to reimburse pharmacies the ASP of a drug. This proposal intends to align pharmacy reimbursement with pharmacy acquisition cost and would be consistent with Medicare reimbursement for Part B-covered drugs as established by the MMA.

This analysis compares ASP to AWP for 2,077 national drug codes where both ASP and AWP data were available for the third quarter of 2004. We will refer to national drug codes with ASP data as Medicare-covered drugs. Medicare-covered drugs may also be covered under the Medicaid program. We analyzed a subset of these national drug codes (1,481) to compare AMP to AWP by drug type. In addition, we compared WAC to AWP for 1,898 national drug codes.

A companion report, "Medicaid Drug Price Comparisons: Average Manufacturer Price to Published Prices" (OEI-05-05-00240), compares AMP to AWP and WAC for Medicaid-reimbursed prescription drugs. That analysis includes 24,101 national drug codes.

FINDING

Average sales price is substantially lower than average wholesale price for drug codes in this review. For 2,077 national drug codes, the median percentage difference between ASP and AWP is 49 percent. Even when factoring in the discounted AWP most States use to calculate the estimated acquisition cost for Medicaid drugs, ASP is still substantially lower.

The difference between ASP and AWP was greatest for generic drugs. For 704 single source brand codes, ASP is 26 percent below AWP at the

median, and for 216 multisource brand codes, ASP is 30 percent below AWP at the median. For 1,152 generic national drug codes, ASP is 68 percent less than AWP at the median. For five drug codes, there was no drug type information in the drug compendium.

To determine if the difference between the analyzed prices were similar for Medicare and Medicaid drugs, we compared the results of our analysis for Medicare-covered drugs to the analysis for Medicaid-reimbursed drugs in our companion report. The companion report “Medicaid Drug Price Comparisons: Average Manufacturer Price to Published Prices” (OEI-05-05-00240) examined the differences between AMP and AWP for all drugs reimbursed by Medicaid (24,101 national drug codes).

We found that the differences between AWP and other prices analyzed are similar for both Medicare and Medicaid drugs. For the 1,481 codes that had AMP and AWP in our review, we found that the difference between AMP and AWP for generic drugs is 72 percent at the median; correspondingly, the companion report found that the difference between AMP and AWP for generic drugs is 70 percent at the median. For single source and multisource brand drugs, this report found that the differences between AMP and AWP are 22 and 25 percent at the median, respectively. Similarly, the companion report found that the differences between AWP and AMP for single source and multisource brand drugs are 23 and 28 percent at the median, respectively.

CONCLUSION

There is significant interest in changing Medicaid reimbursement for prescription drugs by aligning pharmacy reimbursement more closely with pharmacy acquisition cost. The changes proposed in the President’s 2006 budget would make Medicaid reimbursement consistent with Medicare by basing reimbursement on actual sales transactions. This analysis demonstrates that ASP, which is a statutorily defined price based on actual sales transactions including discounts, was lower than published prices AWP and WAC.

We believe this inspection will provide useful information to those considering the implications of changing Medicaid’s drug reimbursement methodology. The substantial disparities between prices based on actual sales and the published prices currently being used indicate that changing the basis of Medicaid reimbursement could have a significant impact on Medicaid expenditures.

AGENCY COMMENTS

CMS commented that these companion reports make clear that current Medicaid payment rules result in overpayments for drugs and emphasizes the need for reform. Similar problems with overpayments for Medicare drugs led to passage of the MMA provisions that changed the basis of reimbursement for drugs from AWP to ASP. CMS reiterated that the President's 2006 budget proposes to solve this problem by the use of ASP so Medicaid drug prices will reflect actual costs. CMS stated that Congress should enact legislation to ensure that Medicaid payment for drugs is related to actual prices paid by pharmacies. The full text of CMS's comments are provided in Appendix A.



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OBJECTIVE

To compare average sales price (a statutorily defined price based on actual sales transactions) to average wholesale price (the published price most States use to set Medicaid reimbursement rates) for Medicare-covered drugs.

BACKGROUND

Increases in Medicaid's prescription drug costs have generated considerable attention from the Administration, Congress, and the States. The House Energy and Commerce Subcommittee on Oversight and Investigations held a hearing in December 2004 on "Medicaid Prescription Drug Reimbursement: Why the Government Pays Too Much" and explored potential reforms.¹ Congress has established a Medicaid commission to provide recommendations to achieve \$10 billion in overall Medicaid savings over the next 5 years and to consider longer-term performance goals and recommendations.² The National Governors Association is also working on proposals to reduce Medicaid spending, including spending on prescription drugs.³

The Office of Inspector General (OIG) and others have found evidence that because States lack accurate drug pricing data, Medicaid drug reimbursements overestimate pharmacies' actual acquisition costs. OIG has also found that Medicaid drug reimbursements exceed the prices paid by other Federal programs. OIG has recommended that Medicaid should base reimbursement on pricing data that more accurately reflects actual acquisition costs.⁴

The Administration has expressed interest in adopting a reimbursement system for Medicaid that is similar to the Medicare Part B drug reform enacted under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Public Law 108-173). The MMA amended the Social Security Act (the Act) to change the method of reimbursement for prescription drugs from average wholesale price (AWP) to average sales price (ASP).

The President's 2006 budget proposes restructuring Medicaid pharmacy reimbursement to save an estimated \$542 million in fiscal year (FY) 2006 and \$15.1 billion over 10 years.⁵ This budget also proposes to require State Medicaid programs to reimburse pharmacies the ASP of a drug plus a 6 percent fee for storage, dispensing, and counseling. According to the President's budget, this reimbursement methodology

aligns pharmacy reimbursement with pharmacy acquisition cost and is consistent with Medicare reimbursement for Part B-covered drugs as established by the MMA.

Medicaid Reimbursement for Prescription Drugs

The Medicaid program, established under Title XIX of the Act, is administered by States and financed with State and Federal funds. Medicaid pays for medical and health-related assistance for certain vulnerable and needy individuals and families. All 50 States and the District of Columbia provide coverage for prescription drugs under the Medicaid program.

Federal regulations require, with certain exceptions, that State Medicaid reimbursements for prescription drugs not exceed the lower of (1) its estimated acquisition cost plus a dispensing fee, or (2) the provider's usual and customary charge to the public for the drug. CMS allows each State to define estimated acquisition cost.

Average wholesale price and wholesale acquisition cost. Currently, most States estimate acquisition cost by discounting AWP by a certain percentage. A small number of States use wholesale acquisition cost (WAC) plus a percentage markup when calculating estimated acquisition costs. According to information obtained from CMS's Web site, the discount from AWP in the State methodologies ranged from 5 to 50 percent, and the percentage markup to WAC ranged from 5 to 12 percent as of March 2005. The median discount for drugs for States that use AWP to calculate estimated acquisition cost was AWP minus 12 percent. The median percentage markup to WAC for the small number of States that use this price to calculate estimated acquisition cost was 8.5 percent.

The AWP is a price published in commercial publications. It is an important prescription drug pricing benchmark for payers throughout the health care industry. Similarly, the WAC is a price reported in commercial publications. Prior to the MMA, WAC was not a term defined in statute or regulation. The MMA defined WAC as the manufacturer's list price for the drug to wholesalers or direct purchasers, not including prompt pay or other discounts, rebates, or reductions in price, for the most recent month for which information is available.

Previous OIG work demonstrated that the AWP States use to calculate estimated acquisition cost that determine Medicaid drug reimbursement rates are higher than the prices retail pharmacies pay

to purchase drugs.⁶ The AWP is not defined in law or regulation, and fails to account for the discounts available to various payers, including certain Federal agencies, providers, and large purchasers. It is a price derived from manufacturer-reported data for both brand and generic drugs.

According to the President's 2006 Budget, the current Medicaid reimbursement method has created an incentive for manufacturers to artificially raise the AWP to make their products more attractive to pharmacies because the profit will be larger with the higher price. According to Congressional testimony, States continue to rely on AWP, despite its widely recognized deficiencies, because they lack access to more accurate pricing information.

Prior to 2005, Medicare also used AWP as the basis for Part B drug reimbursement. However, numerous reports by OIG and the Government Accountability Office, as well as data collected by the Department of Justice and Congressional investigations, indicated that Medicare's reimbursement rate was significantly higher than the prices that drug manufacturers, wholesalers, and other similar entities actually charge to physicians and suppliers who purchase these drugs. Consequently, the MMA changed the basis of reimbursement for prescription drugs from AWP to ASP.

Medicare Drug Reimbursement Methodologies

Average sales price. In 2005, Medicare began to pay for most drugs using an entirely new methodology based on ASP rather than AWP. Unlike AWP and WAC, there is a specific method to calculate ASP set forth in the MMA and the Act. Section 1847A(c) of the Act, as amended by the MMA, defines ASP as a manufacturer's unit sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of drug units sold by the manufacturer in that same quarter. The ASP is net of any price concessions such as volume, prompt pay, and cash discounts; free goods contingent on purchase requirements; chargebacks; and rebates other than those obtained through the Medicaid drug rebate program. Certain sales are exempt from the calculation of ASP, including sales at a nominal charge.

Manufacturers report ASPs to the Centers for Medicare & Medicaid Services (CMS) on a quarterly basis by national drug code, which is an 11-digit identifier that indicates the manufacturer of the drug, the product dosage form, and the package size. Third quarter 2004 ASP submissions to CMS from manufacturers served as the basis for first

quarter 2005 Medicare allowances for most covered drug codes. As of January 1, 2005, Medicare's allowance for most covered outpatient drug codes is equal to 106 percent of the volume-weighted ASPs for those drugs.

The Medicaid Drug Rebate Program

Average manufacturer price. Similar to ASP, average manufacturer price (AMP) is defined by law and based on actual sales transactions. In order for a manufacturer's drug to be eligible for Federal Medicaid matching funds, section 1927(a)(1) of the Act mandates that drug manufacturers enter into rebate agreements with the Secretary and pay quarterly rebates to State Medicaid agencies. Under these rebate agreements and the law, manufacturers must provide CMS with the AMP for each of their national drug codes on a quarterly basis. Medicaid calculates drug rebates based on AMP. Section 1927(k)(1) of the Act defines AMP to be the average price paid to the manufacturer by wholesalers in the United States for drugs distributed to the retail pharmacy class of trade minus customary prompt pay discounts. The AMP is calculated as a weighted average of prices for all of a manufacturer's package sizes of a drug sold during a given quarter and is reported for the lowest identifiable quantity of the drug (e.g., one milligram, one milliliter, one tablet, one capsule).

Companion Report

A companion report: "Medicaid Drug Price Comparisons: Average Manufacturer Price to Published Prices" (OEI-05-05-00240), examines the differences between AWP, WAC, and AMP for all Medicaid-reimbursed drug codes (24,101 national drug codes). For comparability, we also examined the differences between AMP, WAC, and AWP for national drug codes with ASP values. This comparison would determine if there were substantial price differences for Medicaid-reimbursed drugs and our smaller subset of Medicare-covered drugs.

METHODOLOGY

This analysis compares ASP to AWP for 2,077 national drug codes where both ASP and AWP data were available for the third quarter of 2004. We will refer to national drug codes with ASP data as Medicare-covered drugs. Medicare-covered drugs may also be covered under the Medicaid program. We also analyzed a subset of these national drug codes (1,481) where both AMP and AWP were available. In addition, we analyzed 1,898 codes where both WAC and AWP were available. We

analyzed these subsets of codes to determine how the differences between the price points for Medicare-covered drugs would compare to the differences for Medicaid-reimbursed drugs found in our companion report.

Centers for Medicare & Medicaid Services Data

We obtained ASP and AMP data for third quarter 2004 from CMS.

Average sales price data. We obtained ASPs for 2,113 national drug codes that CMS used in its calculation of volume-weighted ASP for Medicare reimbursement. When calculating the ASPs, CMS only includes national drug codes with ASP submissions that are deemed acceptable. We did not examine the national drug codes that CMS opted to exclude from its calculation. These ASPs were based on data submitted by manufacturers for the third quarter of 2004.

We did not verify the accuracy of the billing units information contained in CMS's ASP data; however, OIG may review this information as part of a future study.

Average manufacturer price data. For the 2,113 national drug codes that had ASP data, we also obtained AMP data from CMS for the third quarter of 2004. We determined that 1,500 of these national drug codes had usable AMPs. We used a national drug code's AMP when (1) CMS used the code in its calculation of volume-weighted ASP, and (2) we could successfully identify the amount of drug that the code's AMP represented.

An AMP is reported for the lowest identifiable quantity of the drug contained in the national drug code (e.g., one milligram, one milliliter, one tablet, one capsule). In contrast, we obtained ASP, AWP, and WAC data for the entire amount of the drug contained in the national drug code (e.g., for 50 milliliters, for 100 tablets). To ensure that all prices were for comparable units, we converted each AMP so that it represented the total amount of the drug contained in that code. To accomplish this, we multiplied the AMPs for these 1,500 national drug codes by the total amount of the drug contained in each code, as identified by sources such as the CMS crosswalk file, "Red Book," manufacturer Web sites, and the Food and Drug Administration's national drug code directory.

Drug Compendium Data

We obtained AWP and WAC package prices for third quarter 2004 from a national drug compendium. This compendium's drug databases contain national drug codes, drug names, product description, and pricing information, including AWP and WAC.

Since we obtained monthly data for AWP and WAC, we selected a price from 1 month of third quarter 2004 for both price types. To be conservative, we selected the minimum quarterly AWP per national drug code and maximum quarterly WAC per national drug code for this analysis.

Third quarter 2004 average wholesale price and wholesale acquisition cost.

We obtained AWP and WAC prices per national drug code for third quarter 2004 because the ASP and AMP prices we collected are based on manufacturer submissions for the third quarter of 2004. From the 2,113 national drug codes for which we had ASP data, we found 2,079 codes with AWP data and 1,899 with WAC data.

Average Sales Price Comparison

We created one data set that contained ASP and AWP data for all drugs under review. We excluded from our analysis codes that did not have information for both ASP and AWP. We also excluded two codes where the ASP was zero. As a result of this, there were 2,077 unique national drug codes included in our comparison of ASP to AWP.

We used AWP as our point of comparison because most States calculate estimated acquisition cost based on AWP minus some percentage. For each of the 2,077 national drug codes, we calculated the percentage difference between ASP and AWP. We calculated the median percentage difference for these 2,077 codes under review.

We also calculated the median percentage differences for single source, innovator multiple source, and non-innovator multiple source drugs. Hereafter, we will refer to single source as single source brand; innovator multiple source as multisource brand; and non-innovator multiple source as generic. We identified each drug type for these categories based on information in the drug compendium. For five codes, there was no drug type information in the drug compendium. We excluded these five codes from our analysis of drug type. We did not verify the data from the compendium.

Comparisons of Other Price Points

We analyzed a subset of codes to determine how the differences between the price points for Medicare-covered drugs would compare to the differences for Medicaid-reimbursed drugs found in our companion report. Out of the 2,077 drug codes we reviewed, we compared AMP to AWP for the 1,483 codes where both prices were available. For two of these codes, there was no drug type information in the drug compendium. We excluded these codes from our analysis of drug type. For each of the 1,481 codes in this subset, we calculated the median percentage difference between AMP and AWP for each drug type. For this analysis of Medicare-covered drugs, we did not use the same drug compendium for AWP and WAC data as the companion report.

Out of the 2,077 drug codes we reviewed, we compared WAC to AWP for the 1,898 codes where both prices were available. For each code in this subset, we calculated the median percentage difference between WAC and AWP for each drug type.

Limitations

We intend this inspection to provide information that is useful to those who are considering changing the basis of Medicaid reimbursement from a published price to a price based on actual sales. However, our analysis compares price points and not actual reimbursements. It is a theoretical analysis that is useful to estimate the impact of such a reimbursement change, but it does not measure the actual impact of such a change for two main reasons. First, States do not always reimburse at the amount that their estimated acquisition cost formulas would predict. Our analysis does not capture the full complexity of Medicaid reimbursement, which can include tiered estimated acquisition cost formulas as well as other price points (i.e., usual and customary charge, Federal upper limits, and State maximum allowable costs). Second, we are comparing published prices to ASP. However, if the basis of Medicaid reimbursement were changed to ASP, it would likely be ASP plus a markup percentage. For example, Medicare Part B now reimburses prescription drugs at ASP plus 6 percent.

Standards

This study was conducted in accordance with the “Quality Standards for Inspections” issued by the President’s Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency.

F I N D I N G

Average sales price is substantially lower than average wholesale price for drug codes in this review

The ASP, a statutorily defined price based on actual sales transactions including discounts, is substantially lower than AWP. For

2,077 national drug codes with ASP and AWP data, ASP is 49 percent lower than AWP at the median.

For the purposes of Medicaid reimbursement, most States estimate acquisition cost by discounting AWP by a percentage ranging from 5 to 50 percent. The median discount for States that use AWP to calculate estimated acquisition cost drugs was 12 percent below AWP. Even when taking into account the discounted AWP most States use to calculate estimated acquisition cost, ASP is still substantially lower than AWP.

The ASP for generic drugs was substantially less than AWP when compared to single source and multisource brand drugs.

We analyzed the median percentage differences between ASP and AWP by type of drug: single source brand, multisource brand, and generic. For 704 single source brand codes, ASP is 26 percent below AWP at the median, and for 216 multisource brand codes, ASP is 30 percent below AWP at the median. The difference between ASP and AWP was greatest for generic drugs. For 1,152 generic national drug codes, ASP is 68 percent less than AWP at the median. For five drug codes, there was no drug type information in the drug compendium.

The differences between AWP and other prices are similar for both Medicaid-reimbursed drugs and the smaller subset of Medicare-covered drugs we reviewed.

To determine if the differences between the price points were similar for Medicare and Medicaid drugs, we compared the results of our analysis for Medicare-covered drugs to the analysis for Medicaid-reimbursed drugs in our companion report. Medicare-covered drugs may also be covered under the Medicaid program.

The companion report “Medicaid Drug Price Comparisons: Average Manufacturer Price to Published Prices” (OEI-05-05-00240) examined the differences between AMP and AWP for drugs reimbursed by Medicaid (24,101 national drug codes). The companion report’s findings for Medicaid-reimbursed drugs were similar to this report’s finding for the subset of Medicare drugs we reviewed. It found that the difference between AMP and AWP was greatest for generic drugs.

F I N D I N G

For the 1,481 codes that had AMP and AWP in our review, we found that the difference between AMP and AWP for generic drugs is 72 percent at the median; correspondingly, the companion report found that the difference between AMP and AWP for generic drugs is 70 percent at the median. For single source and multisource brand drugs, this report found that the differences between AMP and AWP at the median are 22 and 25 percent, respectively. Similarly, the companion report found that the differences between AWP and AMP for single source and multisource brand drugs at the median are 23 and 28 percent, respectively.

The companion report also found similar differences between WAC and AWP. For the 1,898 codes that had AWP and WAC in our review, we found WAC is 20 percent lower than AWP for Medicare drugs at the median and the companion report found that WAC is 22 percent lower than AWP for Medicaid-reimbursed drugs at the median.



C O N C L U S I O N

There is significant interest in changing Medicaid reimbursement for prescription drugs by aligning pharmacy reimbursement more closely with pharmacy acquisition cost. The changes proposed in the President's 2006 budget would make Medicaid reimbursement consistent with Medicare by basing reimbursement on actual sales transactions. This analysis demonstrates that ASP, which is a statutorily defined price based on actual sales transactions including discounts, was lower than published prices AWP and WAC.

We believe this inspection will provide useful information to those considering the implications of changing Medicaid's drug reimbursement methodology. The substantial disparities between prices based on actual sales and the published prices currently being used indicate that changing the basis of Medicaid reimbursement could have a significant impact on Medicaid expenditures.

AGENCY COMMENTS

CMS commented that these companion reports make clear that current Medicaid payment rules result in overpayments for drugs and emphasizes the need for reform. Similar problems with overpayments for Medicare drugs led to passage of the MMA provisions that changed the basis of reimbursement for drugs from AWP to ASP. CMS reiterated that the President's 2006 budget proposes to solve this problem by the use of ASP so Medicaid drug prices will reflect actual costs. CMS stated that Congress should enact legislation to ensure that Medicaid payment for drugs is related to actual prices paid by pharmacies. The full text of CMS's comments are provided in Appendix A.

► A P P E N D I X ~ A

Centers for Medicare & Medicaid Services' Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: JUN 21 2005

TO: Daniel R. Levinson
Acting Inspector General

FROM: Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: OIG Draft Reports: "Comparison of Medicaid Federal Upper Limit Amounts to Average Manufacturer Prices," (OEI-03-05-00110);

"Medicaid Drug Price Comparison: Average Sales Price to Average Wholesale Price," (OEI 03-05-00200); and

"Medicaid Drug Price Comparison: Average Manufacturer Price to Average Wholesale Price," (OEI-05-05-00240)

Thank you for the opportunity to review and comment on the Office of Inspector General's (OIG) draft reports entitled "Comparison of Medicaid Federal Upper Limit Amounts to Average Manufacturer Prices," "Medicaid Drug Price Comparison: Average Sales Price to Average Wholesale Price," and "Medicaid Drug Price Comparison: Average Manufacturer Price to Average Wholesale Price." The first OIG report addresses how prices for drugs set under the Medicaid Federal Upper Limit (FUL) program compare to reported average manufacturer prices (AMP), and estimates potential savings if FUL amounts were based on reported AMPs. The latter two reports compare how prices that most states currently use to set Medicaid reimbursement, average wholesale price (AWP), and wholesale acquisition cost (WAC), compare to statutorily defined prices based on actual sales transactions, i.e., average sales price (ASP) and AMP.

The OIG reports make clear that the current payment rules result in overpayments for drugs and emphasize the need for reform. The President's 2006 budget proposes to solve this problem by the use of average sales prices (ASP) so Medicaid drug prices will reflect actual costs.

OIG Recommendation

CMS should work with Congress to set Medicaid drug reimbursement amounts that more closely approximate pharmacy acquisition cost.

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CMS Response

We concur with the OIG that the Congress needs to address drug prices paid by Medicaid to more closely relate Medicaid reimbursement to actual transaction prices.

Federal regulation (42 CFR 447.332) requires the FUL amount to be 150 percent of the published price for the least costly therapeutic equivalent using data from all available national compendia. The FUL system selects the lowest price of AWP, WAC, or direct price (DP), as reported by the national compendia to arrive at the FUL price.

States reimburse pharmacies for single source drugs at the lower of Estimated Acquisition Cost (EAC), or the pharmacy's usual and customary charge (UCC) to the general public. EAC is based on the state's reimbursement formula, generally AWP minus a percentage or WAC plus a percentage.

Neither AWP nor WAC is related to the market price of drugs. Rather, they are prices based on reports by manufacturers. Manufacturers often report inflated prices in order to increase the profit for pharmacies and, thereby, encourage pharmacies to dispense their product. State Medicaid Agencies need information on market prices in order to set appropriate payment rates. The President has proposed in the fiscal year 2006 budget to require drug manufacturers to report ASP for drugs and to cap Federal matching for drug expenditures, in the aggregate, to ASP plus 6 percent.

OIG Findings

Overall, FUL prices were five times higher than the average AMPs for generic drug products in the third quarter of 2004. If Medicaid based FUL amounts on 150 percent of the average AMP instead of the compendia prices, the program could have saved an estimated \$161 million in the third quarter of 2004.

For the comparison of AMP to compendia price, AMP is substantially lower than both AWP and WAC for all National Drug Codes (NDCs) reviewed. The median price comparison for all evaluated drugs was that AMP is equal to AWP – 59 percent and AMP is equal to WAC - 25 Percent. Generic drugs exhibited the largest differences between AMP and the list prices – The median price comparison for generic drugs was AMP is equal to AWP - 70 percent and AMP is equal to WAC – 40 percent. States' median AWP based estimated acquisition cost is AWP – 12 Percent. States' median WAC based estimated acquisition cost is WAC plus 8.5 percent.

For the comparison of ASP to compendia price, ASP is substantially lower than AWP and WAC for all NDCs reviewed. For 2,077 NDCs with ASP and AWP data, ASP is equal to AWP – 49 percent. The difference between ASP and AWP was greatest for generic drugs. For 1,152 generic NDCs, ASP is equal to AWP – 68 Percent.

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CMS Response/Conclusion

These reports provide additional supportive evidence that when published compendia prices are used as a basis for Medicaid drug reimbursement, Medicaid payment greatly exceeds actual acquisition cost. Legislation would be needed to define a price that manufacturers must report that can be used as a basis for state Medicaid agencies to set pharmacy payment.

In the fiscal year 2006 budget, the President proposed to require drug manufacturers to report the ASP for each drug and to cap Federal payment at an aggregate level to ASP plus 6 percent. As long as states must rely on prices that are not based on true prices paid to manufacturers, states have no means to set appropriate payment amounts. Current WACs and AWP are greatly inflated and this inflation is encouraged by setting Medicaid payment in relation to these inflated prices. Requiring manufacturers to report true prices and to limit Medicaid payment to a reasonable amount above these prices will eliminate the opportunity for manufacturers and pharmacies to gain through the reporting of inflated prices, yield substantial state and Federal government savings, and retain flexibility for states to set prices for individual drugs as they find appropriate within the overall cap.

Prior to 2005, Medicare also used AWP as the basis for Part B drug reimbursement. However, numerous studies by the OIG and the Government Accountability Office, (GAO), indicated that Medicare's reimbursement rate was significantly higher than the prices that drug manufacturers and wholesalers actually charged physicians and suppliers who purchased these drugs. Consequently, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) changed the basis of reimbursement for prescription drugs from AWP to ASP. Congress should now enact similar legislation to ensure that Medicaid payment for drugs is related to actual prices paid by pharmacies.



E N D N O T E S

¹ Testimony transcript available at:

<http://www.oig.hhs.gov/testimony/docs/2004/reeb120704.pdf>.

² Federal Register Notice. Medicaid Program; Establishment of the Medicaid Commission and Request for Nominations for Members. CMS-2214-N.

³ Available online at www.nga.org.

⁴ “Variations in State Medicaid Drug Prices” (OEI-05-02-00681); “Cost Containment of Medicaid HIV/AIDS Drug Expenditures”(OEI-05-99-00611); “Medicaid Pharmacy—Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products” (A-06-02-00041).

⁵ United States House of Representatives Committee on the Budget. “Analysis of the President’s Budget for FY 2006.” Available at: <http://www.house.gov/budget/analysisprez021105.pdf>.

⁶ “Medicaid Pharmacy – Actual Acquisition Cost of Prescription Drug Products for Brand Name Drugs” (A-06-96-00030); “Medicaid Pharmacy – Actual Acquisition Cost of Generic Prescription Drug Products” (A-06-97-00011); “Actual Acquisition Cost of Brand Name Prescription Drug Products” (A-06-00-00023); “Medicaid Pharmacy – Actual Acquisition Cost of Generic Prescription Drug Products” (A-06-01-00053); “Medicaid Pharmacy – Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products” (A-06-02-00041); “Medicaid’s Use of Revised Average Wholesale Prices” (OEI-03-01-00010); “Containment of Medicaid HIV/AIDS Drug Expenditures” (OEI-05-99-00611).



A C K N O W L E D G M E N T S

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